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510(k) Summary
Ovusoft TCOYF
(as specified in 21 CFR 807.92)

1. SPONSOR

Ovusoft, Inc.
402 Dunham Massie Drive
Hampton, Virginia 23669

Contact Person: Gene Grant
Telephone: 757-851-2228

Date Prepared: August 29, 2000

2. DEVICE NAME

Proprietary Name: TCOYF Fertility Software
Common/Usual Name: Fertility software
Classification Name: Fertility Diagnostic Device

3. PREDICATE DEVICES

Fertility Forecaster K880618

4. DEVICE DESCRIPTION

The Ovusoft TCOYF Fertility Software consists of a software application that runs on a computer and accepts various data inputs from the user. The device determines days of peak fertility and estimates the ovulation date in each cycle. It also analyzes whether the user may be pregnant based on her temperature observations.

5. INTENDED USE

The Ovusoft TCOYF is a stand alone software program to be used by women as an aid to conception by identifying those days in a woman's cycle on which intercourse is most likely to lead to conception via an analysis of her temperature and cervical fluid. Properly used, it will reduce the time it takes to achieve pregnancy. It is not to be used for contraception (i.e. birth control).

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

	TCOYF Fertility Software	Fertility Forecaster
Indications for use	Aid to conception	Aid to conception
Target population	Couples trying to conceive	Couples trying to conceive
Algorithms used	Automation of Fertility Awareness Method	Automation of Fertility Awareness Method
Year 2000 Compliance	Fully compliant	Not compliant at all (displays "2000" as "100")
Design	Windows-based computer program with graphical user interface. Accepts user inputs for menstruation, intercourse, basal body temperature, cervical mucus, etc.	DOS-based computer program with non-graphical user interface. Accepts user inputs for menstruation, intercourse, basal body temperature, cervical mucus, etc.
Materials	Delivered electronically via the Internet and via "shrink-wrap" CD-ROM. Shrink-wrap version includes a printed manual, downloaded version includes manual in electronic form.	Diskette and printed manual.
Performance (refer to detailed performance comparison with predicate in Section 4 of this 510(k))	Uses Fertility Awareness Method rules (sympto-thermal natural family planning) to determine start and end of fertile phase. Fertility determinations are made from the first day of use. User may skip days of entry without penalty.	Uses Fertility Awareness Method rules to determine start and end of fertile phase. No fertility determinations made for 2-3 weeks of initial usage or if user fails to enter 4 temperatures in a row. User must enter temperatures **every** day they make any entry.
Human factors	User-friendly with ability to "undo" changes, make backups easily, correct user misinterpretation of fertility signs.	Inability to undo changes, no backup method provided, must use diskette provided with program at all times, cannot determine when user may have misinterpreted data.
Energy used	None, other than that required to run a personal computer.	None, other than that required to run a personal computer.
Compatibility with other devices	Compatible with Windows-based PCs.	Compatible with MS-DOS-based PCs.
Where used	Home	Home
Standards met	Windows 95/98/NT/2000	MS-DOS

7. PERFORMANCE TESTING

Testing of the Ovusoft TCOYF included in this 510(k) consists of software verification and validation and comparison of results with those generated by the Fertility Forecaster. Results demonstrate that the Ovusoft TCOYF fulfills

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performance specifications and results are equivalent to those obtained with the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Eugene M. Grant
CEO
Ovusoft, Inc.
402 Dunham Massie Drive
HAMPTON VA 23669

Re: K002726
TCOYF Fertility Software Version 1.0
Dated: February 27, 2001
Received: February 28, 2001
Regulatory Class: Unclassified
Procode: 85 LHD

Dear Mr. Grant:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Statement of Indications for Use

Applicant: Ovusoft, Inc.

510(k) Number (if known): (not known) K002726

Device Name: TCOYF Fertility Software

Indications For Use:

TCOYF Fertility Software is intended to be used by women as an aid to conception by identifying those days in a woman's cycle on which intercourse is most likely to lead to conception via an analysis of her temperature and cervical fluid.

The device consists of a software application that runs on a computer and accepts various data inputs from the user. The device determines days of peak fertility and estimates the ovulation date in each cycle. It also analyzes whether the user may be pregnant based on her temperature observations.

The target market for TCOYF Fertility Software is women who are trying to achieve pregnancy.

It is not intended to be used as a method of birth control. Properly used, it can help reduce the time it takes to achieve pregnancy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002726

Over-the-Counter Use ✓